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properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(1)(1) Each person required under sections 302 and 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated ergocristine and its salts, including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing ergocristine and its salts pursuant to §1310.13 on or before May 2, 2011. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing ergocristine and its salts whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(m)(1) Each person required by Sections 302 or 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated chemical mixtures which contain red phosphorus, white phosphorus, hypophosphorous acid (and its salts), pursuant to §§1310.12 and 1310.13, is temporarily exempted from

the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption on or before July 5, 2011. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture which contains red phosphorus, white phosphorus, hypophosphorous acid (and its salts) whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

[62 FR 27693, May 21, 1997, as amended at 62 FR 53960, Oct. 17, 1997; 65 FR 21647, Apr. 24, 2000; 66 FR 52675, Oct. 17, 2001; 68 FR 23203, May 1, 2003; 69 FR 74971, Dec. 15, 2004; 72 FR 20046, Apr. 23, 2007; 72 FR 35931, July 2, 2007; 72 FR 40239, July 24, 2007; 72 FR 40744, July 25, 2007; 75 FR 37306, June 29, 2010; 76 FR 17781, Mar. 31, 2011; 76 FR 31829, June 2, 2011; 77 FR 4237, Jan. 27, 2012]

§ 1310.10 Removal of the exemption of drugs distributed under the Federal Food, Drug and Cosmetic Act.

(a) The Administrator may remove from exemption under paragraph (1)(iv) of the definition of regulated transaction in §1300.02 of this chapter any drug or group of drugs that the Administrator finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance. In removing a drug or group of drugs from the exemption the Administrator shall consider:

(1) The scope, duration, and significance of the diversion;

(2) Whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(3) Whether the listed chemical can be readily recovered from the drug or group of drugs.

(b) Upon determining that a drug or group of drugs should be removed from the exemption under paragraph (a) of this section, the Administrator shall issue and publish in the FEDERAL REGISTER his proposal to remove the drug or group of drugs from the exemption, which shall include a reference to the legal authority under which the proposal is based. The Administrator shall permit any interested person to file written comments on or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the FEDERAL REGISTER his final order.

(c) The Administrator shall limit the removal of a drug or group of drugs from exemption under paragraph (a) of this section to the most identifiable type of the drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) Any manufacturer seeking reinstatement of a particular drug product that has been removed from an exemption may apply to the Administrator for reinstatement of the exemption for that particular drug product on the grounds that the particular drug product is manufactured and distributed in a manner that prevents diversion. In determining whether the exemption should be reinstated the Administrator shall consider:

(1) The package sizes and manner of packaging of the drug product;

(2) The manner of distribution and advertising of the drug product;

(3) Evidence of diversion of the drug product;

(4) Any actions taken by the manufacturer to prevent diversion of the drug product; and

(5) Such other factors as are relevant to and consistent with the public health and safety, including the factors

described in paragraph (a) of this section as applied to the drug product.

(e) Within a reasonable period of time after receipt of the application for reinstatement of the exemption, the Administrator shall notify the applicant of his acceptance or non-acceptance of his application, and if not accepted, the reason therefor. If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER his order on the reinstatement of the exemption for the particular drug product, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any such comments raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(f) Unless the Administrator has evidence that the drug product is being diverted, as determined by applying the factors set forth in paragraph (a) of this section, and the Administrator so notifies the applicant, transactions involving a specific drug product will not be considered regulated transactions during the following periods:

(1) While a bonafide application for reinstatement of exemption under paragraph (d) of this section for the specific drug product is pending resolution, provided that the application for reinstatement is filed not later than 60 days after the publication of the final order removing the exemption; and

(2) For a period of 60 days following the Administrator's denial of an application for reinstatement.

(g) An order published by the Administrator in the FEDERAL REGISTER, pursuant to paragraph (e) of this section, to reinstate an exemption may be modified or revoked with respect to a particular drug product upon a finding that:

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(1) Applying the factors set forth in paragraph (a) of this section to the particular drug product, the drug product is being diverted; or

(2) There is a significant change in the data that led to the issuance of the final rule.

[60 FR 32461, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997; 67 FR 14862, Mar. 28, 2002; 75 FR 38922, July 7, 2010; 77 FR 4237, Jan. 27, 2012]

§ 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.

(a) The Administrator has reinstated the exemption for the drug products listed in paragraph (e) of this section from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–823, 830, and 957–958), to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No reinstated exemption granted pursuant to § 1310.10 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in exempt drug product compositions: Any change in the quantitative or qualitative composition, trade name or other designation of an exempt drug product listed in paragraph (d) requires a new application for reinstatement of the exemption.

(d) The following drug products, in the form and quantity listed in the application submitted (indicated as the “date”) are designated as reinstated

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exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS

Supplier	Product name	Form	Date
[Reserved]	

[60 FR 32462, June 22, 1995]

§ 1310.12 Exempt chemical mixtures.

(a) The chemical mixtures meeting the criteria in paragraphs (c) or (d) of this section are exempted by the Administrator from application of sections 302, 303, 310, 1007, 1008, and 1018 of the Act (21 U.S.C. 822, 823, 830, 957, 958, and 971) to the extent described in paragraphs (b) and (c) of this section.

(b) No exemption granted pursuant to this § 1310.12 or § 1310.13 affects the criminal liability for illegal possession, distribution, exportation, or importation of listed chemicals contained in the exempt chemical mixture or the civil liability for unlawful acts related to exempt chemical mixtures, including distribution in violation of 21 U.S.C. 842(a)(11).

(c) Mixtures containing a listed chemical in concentrations equal to or less than those specified in the “Table of Concentration Limits” are designated as exempt chemical mixtures for the purpose set forth in this section. The concentration is determined for liquid-liquid mixtures by using the volume or weight and for mixtures containing solids or gases by using the unit of weight.

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
List I Chemicals			
N-Acetylanthranilic acid, its salts and esters.	8522	20% by Weight	Concentration based on any combination of N-acetylanthranilic acid and its salts and esters.
Anthranilic acid, and its salts and esters.	8530	50% by Weight	Concentration is based on any combination of anthranilic acid and its salts and esters.
Benzaldehyde	8256	50% by Weight or Volume.	
Benzyl cyanide	8570	20% by Weight or Volume.	
Ephedrine, its salts, optical isomers, and salts of optical isomers.	8113	Not exempt at any concentration.	Chemical mixtures containing any amount of ephedrine and/or pseudoephedrine, and their salts, optical isomers and salts of optical isomers are not exempt due to concentration, unless otherwise exempted.
Ergocristine and its salts	8612	Not exempt at any concentration.	Chemical mixtures containing any amount of ergocristine and its salts are not exempt.
Ergonovine and its salts	8675	Not exempt at any concentration.	Chemical mixtures containing any amount of ergonovine, including its salts, are not exempt.